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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/265,237	06/23/94	BACKSTROM	K 06275004001

PRICKERT, T. EXAMINER

18N1/0424

ART UNIT	PAPER NUMBER
1813	11

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No. <b>08/265,237</b>	Applicant(s) <b>Backstrom</b>
Examiner <b>Benet Prickril</b>	Group Art Unit <b>1813</b>

Responsive to communication(s) filed on Nov 8, 1995

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

Claim(s) 1-32 is/are pending in the application.

Of the above, claim(s) 23-25 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1-22 and 26-32 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

Claims \_\_\_\_\_

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 10

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

... SEE OFFICE ACTION ON THE FOLLOWING PAGES ...

### Part III DETAILED ACTION

#### *Status of Claims*

1. Claims 1-32 are pending in this Office action. Claims 23-25 are withdrawn as being drawn to a nonelected invention.

2. The amendment filed November 8, 1995 requests replacement of Table I with the substitute page "Exhibit A". No Exhibit A was included with the papers as entered. However, the spelling of "Didecanoylphosphatidylcholine" at line 10 of Table I has been corrected. Any further changes to the table should be made by an additional amendment or replacement Table I.

#### *Response to Amendment*

3. The rejection of claims 2, 4, 12 and 27 under 35 U.S.C. § 112, second paragraph is withdrawn with respect to claim 2 due to amendment to the claim, and maintained with respect to claims 4, 12, and 27 for the reasons cited in the previous Office action (paper No. 7). Applicant's arguments filed November 8, 1995 have been fully considered but they are not deemed to be persuasive. The term "analogue" fails to impart reasonable limits upon what is being claimed because this term is by nature nebulous. Analogues of vasopressin, for example, are not limited in any way to a certain percentage of sequence homology or even size in comparison to vasopressin. Moreover, the addition of the term "polypeptide" by applicant fails to further limit the meaning of the term, or to define a single class of molecules, because the term "analogue" is subject to various interpretations by those of ordinary skill in the art. A similar line of reasoning applies to the use of the term "derivative" by applicant, since it is unclear what this term is meant to suggest. Contrary to applicant's assertions, the term "derivative" is not recognized in the art as being limited to compounds in which various counterions are used, or to esterified forms, and is not further defined with respect to bile salts at page 4 of the specification. Indeed, a derivative could be considered to be any chemically related species. If applicant wishes to claim the specific forms of derivative outlined in the amendment they should be explicitly stated in the claim

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language (assuming, of course, adequate support in the specification). Thus these terms are unclear and confusing, and fail to satisfy the strictures of the statute.

4. The rejection of claims 1-14, 17-22, and 26-29 under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Platz et al. [U.S. Patent No. 5,284,656] is maintained for the reasons cited in the previous Office action. Applicant's arguments have been fully considered but they are not deemed to be persuasive.

The pharmaceutical compositions of Platz et al. contain a pharmaceutically active dry powder polypeptide and an absorption enhancer for administration via a dry powder inhaler device which meet the specific limitations of applicant's claims, and therefore are considered identical to those disclosed by applicants. At column 4 lines 6-17, for example, Platz discloses a dry powder polypeptide (G-CSF) in the presence of a propellant "with the aid of a surfactant". The propellant does not, of course, change the fact that the preparation is a dry powder, and Platz suggests the use of a fatty acid such as oleic acid or sorbitan trioleate as a surfactant. It would have been clear to the artisan at the time the invention was made that use of a surfactant in the Platz preparations renders the surfactant a *de facto* absorption enhancer since the intent was to maximize absorption of the polypeptide. Moreover, at page 10 lines 21-32 of the specification applicants suggest the use of fatty acid salts as absorption enhancers. Therefore the preparations of Platz do indeed meet the limitations of applicant's claims, or would render these claims obvious due to the specific types of embodiment disclosed by Platz.

5. The rejection of claims 1-3, 5-11, 17, 18, 21, 22, 26, and 28 under 35 U.S.C. § 103 as being unpatentable over Rubsamen [U.S. Patent No. 5,364,838] in view of Platz et al. [U.S. Patent No. 5,284,656] is maintained for the reasons cited in the previous Office action. Platz at column 15 lines 31-34 discloses a formulation containing insulin, a propellant, and oleic acid. As discussed above, the oleic acid would be recognized by the artisan as having the effect of increasing insulin absorption, and therefore would function as an

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enhancer. In view of the Platz et al. reference teaching the required particle size this combination of references renders applicant's invention obvious.

6. The rejection of claims 1, 2, 6-18, 21, 22, and 28-32 under 35 U.S.C. § 103 as being unpatentable over Rubsamen [U.S. Patent No. 5,364,838] in view of Clark et al. [U.S. Patent No. 5,341,800] and further in view of Edman et al. [Advanced Drug Delivery Reviews 8, 165-177 (1992)] and Mishima et al. [J. Pharmacol.-Dyn. 10, 624-631(1987)] is maintained for the reasons cited in the previous Office action [paper No. 7]. Rubsaman and Platz et al. are discussed above. It is not necessary that each of the references used in a rejection under 35 U.S.C. § 103 recite all of the particular aspects of the claimed invention. Rather, if the references taken as a whole suggest the claimed invention they can be used to reject the claims under 35 U.S.C. § 103. In the instant case the claims are rendered obvious with respect to the features detailed in the original rejection [paper No. 7]. For example, the Clark et al. reference is cited in order to illustrate the conventional nature of inhaler devices in the art, and is not intended to suggest, nor need it suggest, inhalable dry powder formulations including a polypeptide and an absorption enhancer. If Clark et al. did suggest these features it would have been used in a rejection under 35 U.S.C. § 102. Similarly, the references of Edman et al. and Clark et al. are illustrative, and are not meant or required to disclose all of the features of the claimed invention.

7. The provisional rejection of claims 1, 2, and 6-19 over 08/265372 is withdrawn in view of applicant's arguments.

8. No claims are allowable.

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9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

*General information regarding further correspondence*

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1813.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Benet Prickril whose telephone number is (703) 305-5933. The examiner normally can be reached Monday through Thursday between 7:30 AM and 5:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christine Nucker, can be reached at 308-4028. The fax phone number for Art Unit 1813 is (703) 305-7362.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*MPW*  
MICHAEL P. WOODWARD  
PRIMARY EXAMINER  
GROUP 1800